AR201-13953

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August 20, 2002

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
P.O. Box 1473
Merrifield, VA 2216

Attn: Chemical Right-to-Know Program

Re: EPA comments on the Test Plan and Robust Data Summary for Dinitrile Category

Dear Administrator Whitman,

E. I. du Pont de Nemours & Company, Inc. received EPA's comments on the test plan and robust data summary for the Dinitrile Category and are pleased to respond. We have considered the recommended revisions to environmental fate and health effects studies, as well as, EPA's specific comments on the robust data summaries. We have revised our submittal as needed on the attached summary sheet. Also included with this submittal is a revised robust data summary.

Please feel free to contact me with any questions or concerns you may have with regards to this submission at Edwin.L.Mongan-1@usa.dupont.com or by phone at 302-773-0910.

Sincerely,

Edwin L. Mongan, III
Manager, Environmental Stewardship
DuPont Safety, Health & Environment

Cc: Charles Auer – U.S. EPA
Office of Pollution Prevention & Toxics
U. S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Physical Chemical and Environmental Fate Data:

EPA comment: EPA suggests that a biodegradation test be conducted on ESN rather than extrapolating from ADN.

Response: The structural similarities between the compounds suggest that the nitrile moieties will have similar biodegradation pathways and that the approach of extrapolating from ADN is valid. No biodegradation testing on ESN is planned.

EPA comment: Submitter should make sure that its reported Partition Coefficient for ESN (0.28) is reasonably accurate or provide measured data.

Response: The low molecular weight and relatively high vapor pressure for ESN suggest that it is likely not an issue for bioaccumulation. It appears that the predicted log Kow for ESN is in line with the properties and predicted Kows for the other 2 compounds. Given these observations, it is unnecessary to measure the log Kow of ESN.

Health Effects

EPA comment: The overall data to support a category approach is weak. The on-going repeated-dose toxicity test of 2-MGN will allow a more complete comparison to existing data for ADN. If this study indicates dissimilar toxicities, the submitter will need to consider whether reproductive and development testing is needed.

Response: Results from the repeated-dose study of 2-MGN were added to the document.

EPA comment: For the acute oral toxicity endpoints, no data were provided for target organs or non-lethal endpoints.

Response: Additional statements were added to the summary.

EPA comment: Dermal and eye irritation studies are not endpoints of the HPV Challenge Program.

Response: These tests were removed from the test plan.

EPA comment: For the robust summaries of acute oral toxicity studies for 2-MGN and ESN, the sponsor needs to provide additional information, including the number and gender of animals tested, the use of controls, the length of the post-observation period, and/or endpoints tested. Based on the information provided, the study design for ESN was inadequate because too few animals were used.

Response: Requested information for 2-MGN study was added to the document. For the acute study for ESN, 5 male and 5 female rats/group were used in the main study. This is an adequate number of animals to address the endpoint.

EPA comment: For the robust summary of the bacterial reverse mutation assay for 2-MGN, the sponsor needs to provide additional information, including potential contaminants in the test substance (purity 85%) and the number or replicates tested. For the robust summary of a mouse micronucleus test for 2-MGN, the sponsor needs to provide additional information, including the use of negative controls and method details.

Response: Where available, data were added to address the missing information.

EPA comment: For the robust summary of the repeated-dose toxicity study for ADN, the submitter needs to provide additional information, including clinical signs, clinical chemistry, and necropsy.

Response: Where available, data were added to address the missing information.

Ecological Effects

EPA comment: All SAR robust summaries failed to provide the octanol/water partition coefficient information by source and the value entered into the ECOSAR program.

Response: Requested data were added to the robust summary.

EPA comment: Missing data elements needed for the ADN aquatic invertebrate study are chemical purity, hardness, and pH and for the ESN study hardness and dissolved oxygen.

Response: Where available, data were added to address the missing information.